REMARKS

This paper amends claims 56-59, 61, 63-65 and 67-69 and cancels claims 60, 62 and 66. Claims 56-59, 61, 63-65 and 67-69 are pending. The amendments introduce no new matter. Provision for extension of time accompanies this response.

35 USC § 112, first paragraph

The Office rejected claims 56-69 under 35 USC § 112, first paragraph as allegedly not enabled. The amended claims also reduce the number of variable groups that are present.

The Office noted that the variable group substituents include polymers. The amended claims do not recite polymers as variable group substituents and this basis for the rejection is now moot.

The Office asserted that when the R^5 variable group was -NH-C(O)-C50 organic moiety and other variable groups were alkyl groups of 50 carbon atoms substituted by proteins there would be good reason to doubt that the compound would have the same activity as another compound where the variable groups were all hydrogen atoms. In making this assertion, which Applicants traverse, the Office has misunderstood the specification's definitions for the variable groups. Terms such as alkyl and substituted alkyl are defined at page 6, line 31 through page 8, line 23. Given the definitions for the variable groups in the specification, it no variable group can be an alkyl group of 50 carbon atoms substituted by a protein.

The basis for and relevance of Office's assertion that one compound would have a different activity than another is unclear. Because the Office did not give any reason other than the assertion that compounds would have different activity levels, Applicants cannot respond with a reasoned rebuttal. And, since there is no requirement for all compounds within the scope of a claim to have the same activity to be patentable, the relevance of this assertion is also not clear.

In considering enablement, the court has stated: "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In Re Miguel F. Brana, et al.* 51 F3d 1560; 34 U.S.P.Q.2D 1436 (C.A.F.C. 1995), citing *In re Marzocchi*, 439 F.2d 220, 223; 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Applicants request the Office to clarify the rational basis for its assertion that enablement is insufficient for this reason.

At page 3 of the office action, the Office asserted that the term androgen responsive disease is not defined. Applicants traverse this characterization. Amended claim 56 recites prostate cancer and benign prostatic hypertrophy and this basis for the rejection is moot.

The Office alleged that despite the data in the specification at pages 77-81, "there was good reason to doubt the effectiveness of the claimed methods based on the in vitro data". The Office stated that there was no evidence that the activity correlates with treatment of the claimed diseases. Applicants submit that the data provides a clear and rational reason to believe that the claimed treatment methods would be useful to treat the claimed diseases conditions. The specification clearly shows that inhibition of activation of the androgen receptor by androst-5-ene-3β,17β-diol, would lead to direct inhibition of tumor cell proliferation. In view of the mechanism of action that the specification describes, there is no reason for one of skill in the art to reasonably doubt the asserted usefulness. Applicants respectfully submit that the Office has not provided evidence showing why one of ordinary skill in the art would reasonably doubt the asserted utility, which should on its face be a rational basis for treatment. Because of this, the Office has not met its burden to establish the rejection. *In re Bundy*, 642 F.2d 430, 433, 209 U.S.P.Q. 48, 51 (C.C.P.A. 1981).

The Office stated that Applicant's response of September 7, 2004 was considered, but not found persuasive. Applicants request clarification of why the response was not persuasive. Without an explanation of why the response was not persuasive, Applicants cannot respond.

The Office alleged that the Miyamoto et al reference (*Proc. Nat'l. Acad. Sci.* USA 100:4440-4444 2003, of record) was considered, but not considered persuasive. Applicants request clarification of why the reference was not persuasive. The reference showed potent inhibition of androgen receptor, which is precisely the mechanism that standard prostate cancer therapies, e.g., hydroxyflutamide treatment, now employ. In fact, example 5 of the specification at page 80 shows inhibition of androgen receptor activity that is more potent than that seen with hydroxyflutamide. This is clear evidence of a desired biological effect that is known to directly correlate with beneficial activity of current therapies. Without a reasoned statement or rationale from the Office, Applicants can not provide a reasoned rebuttal and any comments would be speculation about what defect the Office feels is present. In view of evidence of a relevant biological activity, Applicants request reconsideration and withdrawal of the rejection.

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